510(k) Summary of Safety and Effectiveness

MAR 2 5 2010

General Provisions

Trade Name: AngioDynamics, Inc. Morpheus® SMART PICC CT and Procedure Kit

Classification Name: Percutaneous, Implanted, Long-Term, Intravascular Catheters 80 LJS

Name of Predicate Devices

The following predicate devices have been identified for the 6F Triple Lumen Morpheus® SMART PICC CT and Procedure Kits:

Device Name	510(k) Number	Concurrence Date
AngioDynamics Morpheus® CT PICC and Procedure Kits	K070615 K060887 K041420 K040446 K031626 K030415	May 04, 2007 April 24, 2006 July 26, 2004 March 05, 2004 June 19, 2003 April 30, 2003
Bard Access Systems, Inc. 6 Fr TL PowerPICC® Catheter	K053501	January 13, 2006

Contact Name

Jodi Lynn Frasier
Senior Regulatory Affairs Professional
Access Business Unit
AngioDynamics, Inc
603 Queensbury, NY 12804
(518) 798-1215 ext 1676

Date Summary Prepared

March 01, 2010

Classification

Class II

Performance Standards

No performance standards have been established under Section 514 of the Food, Drug and Cosmetic Act for Percutaneous, Implanted, Long-Term, Intravascular Catheters.

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510(k) Summary of Safety and Effectiveness, Continued

Intended Use and Device Description

The AngioDynamics 6F Triple Lumen Morpheus® SMART PICC CT and Procedure Kit is intended for short or long term peripheral access to the central venous system for intravenous therapy, power injections of contrast media, and allows for central venous pressure monitoring. For blood sampling, infusion, or therapy use a 4 French or larger catheter. For central venous pressure monitoring, it is recommended that a catheter lumen of 20 gauge or larger be used. The device is available as a procedural kit with either a Stylet or a Nitinol Wire.

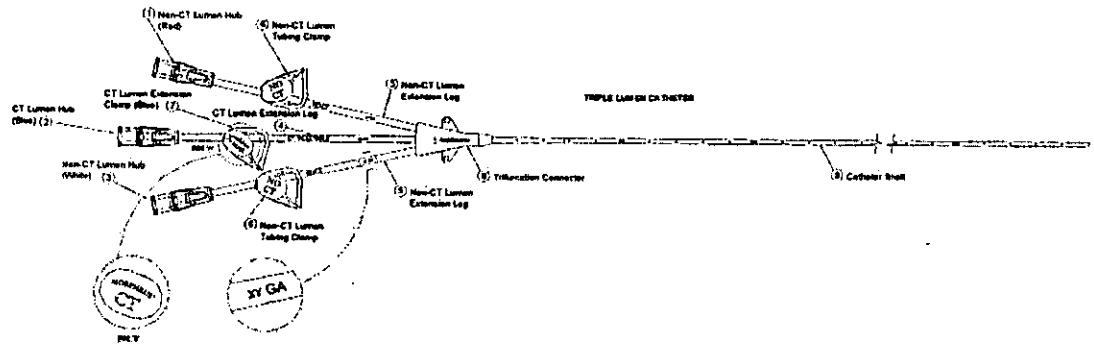
Biocompatibility

The 6F Triple Lumen Morpheus® SMART PICC CT and Procedure Kit have been tested for biocompatibility per ISO 10993. All data demonstrate this device is biocompatible for its intended use.

Summary Comparing Technological Modifications

The AngioDynamics 6F Triple Lumen Morpheus® SMART PICC CT and Procedure Kits device description is as follows:

- 6 French outside diameter, reversed tapered shaft design
- Catheter usable length is 55 cm
- Shaft inner lumen is a triple lumen design
- Catheter shaft tubing is marked with depth indicators
- The catheter has one power injectable lumen
- The product labeling warns against power injection procedures through the two small lumens, which are clearly identified as non CT.
- Three extension legs to facilitate injection through each lumen of the catheter shaft.



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510(k) Summary of Safety and Effectiveness, Continued

Summary Comparing Technological Modifications (continued)

The only modifications that were made are as follows:

- Expand the existing product line to provide a 6F triple lumen catheter shaft. The existing Morpheus® product line currently provides a 6F and 7F Dual lumen catheter design, while
- The catheter shaft is a single durometer material vs. the dual durometer design of the existing product portfolio. The material is the same base material as the distal end of the currently marketed Morpheus® PICC CT and Procedure Kits, with the exception of the barium loading. The 6F triple device will have a 20% Barium loading which is the same as the proximal end of the currently marketed Morpheus® PICC CT and Procedure Kits.
- An additional extension leg has been added to facilitate injection through the third lumen of the catheter shaft. The extension leg materials are identical to those of the currently marketed dual lumen Morpheus® PICC CT and Procedure Kits.
- A natural colored luer will be utilized for the third lumen of the catheter. This luer has identical specifications as those used on the existing Morpheus® PICC CT and Procedure kits and is of the same material. The only difference is the omission of a colorant (red or blue) so that each lumen has a distinctly colored luer for identification purposes.
- Use of a silicone processing aid, for which leave trace amounts may remain on the finished device.

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510(k) Summary of Safety and Effectiveness, Continued

Summary of Verification Activities

The table immediately following outlines the verification/validation activities completed on the proposed device and compares that to the predicate device.

Test	Proposed Device Acceptance Criteria	Proposed 6F Triple Catheter (K093406) T=0	Proposed 6F Triple Catheter (K093406) T=1	Predicate Device Acceptance Criteria	AngioDynamics Morpheus® CT PICC and Procedure Kits (K070615, K060887, K041420, K040446, K031626, K030415) T=0	AngioDynamics Morpheus® CT PICC and Procedure Kits (K070615, K060887, K041420, K040446, K031626, K030415) T=1
Tip Whip	Tip "whipping" is defined as the tip moving from left to right during an injection. Tip whipping must be less than or equal to predicate devices	Pass	Pass	Tip "whipping" is defined as the tip moving from left to right during an injection. Tip whipping must be less than or equal to predicate devices	Pass	Pass
Tip Displacement	Tip displacement is defined as the tip backing-up during an injection. Tip displacement must be less than or equal to predicate devices	Pass	Pass	Tip displacement is defined as the tip backing-up during an injection. Tip displacement must be less than or equal to predicate devices	Pass	Pass

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Summary of Verification Activities (continued)

Test	Proposed Device Acceptance Criteria	Proposed 6F Triple Catheter (K093406) T=0	Proposed 6F Triple Catheter (K093406) T=1	Predicate Device Acceptance Criteria	AngioDynamics Morpheus® CT PICC and Procedure Kits (K070615, K060887, K041420, K040446, K031626, K030415) T=0	AngioDynamics Morpheus® CT PICC and Procedure Kits (K070615, K060887, K041420, K040446, K031626, K030415) T=1
CT Injection – Catheter Flow Rate	Flow Rate = 5mL/sec ± 0.5mL/sec with 95% confidence that 95% of the population meets specification	Pass	Pass	Flow Rate = 3 to 8mL/sec ± 0.5mL/sec (depending on catheter configuration) with 95% confidence that 95% of the population meets specification	Pass	Pass
CT Injection – CT Lumen Integrity	CT Lumen must withstand a minimum of 10 injections at a minimum flow rate of 5mL/sec with a 95% confidence that 80% of the population meets specification	Pass	Pass	CT Lumen must withstand a minimum of 10 injections at a minimum flow rate of 3 to 8mL/sec (depending on catheter configuration) with a 95% confidence that 80% of the population meets specification	Pass	Pass

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Summary of Verification Activities (continued)

Test	Proposed Device Acceptance Criteria	Proposed 6F Triple Catheter (K093406) T=0	Proposed 6F Triple Catheter (K093406) T=1	Predicate Device Acceptance Criteria	AngioDynamics Morpheus® CT PICC and Procedure Kits (K070615, K060887, K041420, K040446, K031626, K030415) T=0	AngioDynamics Morpheus® CT PICC and Procedure Kits (K070615, K060887, K041420, K040446, K031626, K030415) T=1
Aspiration	Minimum aspiration rate to be 3cc/min using a 10cc syringe without total collapse (all three catheter lumens) with 95% confidence that 95% of the population meets specification	Pass	Pass	Minimum aspiration rate to be 3cc/min using a 10cc syringe without total collapse (all three catheter lumens) with 95% confidence that 95% of the population meets specification	Pass	Pass
Gravity Flow Rate	Minimum gravity flow rate to be 750 ml/hr for CT lumen and 182 ml/hr for non-CT lumens with 95% confidence that 95% of the population meets specification	Pass	Pass	Minimum gravity flow rate to be 750 ml/hr for CT lumen and 182 ml/hr for non-CT lumens with 95% confidence that 95% of the population meets specification	Pass	Pass

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Summary of Verification Activities (continued)

Test	Proposed Device Acceptance Criteria	Proposed 6F Triple Catheter (K093406) T=0	Proposed 6F Triple Catheter (K093406) T=1	Predicate Device Acceptance Criteria	AngioDynamics Morpheus® CT PICC and Procedure Kits (K070615, K060887, K041420, K040446, K031626, K030415) T=0	AngioDynamics Morpheus® CT PICC and Procedure Kits (K070615, K060887, K041420, K040446, K031626, K030415) T=1
Stylet Withdrawal Testing	Stylet withdrawal force must be less than 2 lbs with 95% confidence that 95% of the population meets specification	Pass	Pass	Stylet withdrawal force must be less than 2 lbs with 95% confidence that 95% of the population meets specification	Pass	Pass
Wire Withdrawal Testing	Guidewire withdrawal force must be less than 2 lbs with 95% confidence that 95% of the population meets specification	Pass	Pass	Guidewire withdrawal force must be less than 2 lbs with 95% confidence that 95% of the population meets specification	Pass	Pass
Static Burst	Catheter burst pressure must be greater than 150 psi with 95% confidence that 95% of the population meets the specification	Pass	Pass	Catheter burst pressure must be greater than 150 psi with 95% confidence that 95% of the population meets the specification	Pass	Pass

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Summary of Verification Activities (continued)

Test	Proposed Device Acceptance Criteria	Proposed 6F Triple Catheter (K093406) T=0	Proposed 6F Triple Catheter (K093406) T=1	Predicate Device Acceptance Criteria	AngioDynamics Morpheus® CT PICC and Procedure Kits (K070615, K060887, K041420, K040446, K031626, K030415) T=0	AngioDynamics Morpheus® CT PICC and Procedure Kits (K070615, K060887, K041420, K040446, K031626, K030415) T=1
Dynamic Burst	Catheter dynamic burst pressure must be greater than 300 psi with 95% confidence that 95% of the population meets specification	Pass	Pass	Catheter dynamic burst pressure must be greater than 300 psi with 95% confidence that 95% of the population meets specification	Pass	Pass
Tensile Testing						
Extension Leg to Natural Color Hub	Tensile strength must be greater than 5 lbs with 95% confidence that 99% of the population meets the specification	Pass	Pass	Tensile strength must be greater than 5 lbs with 95% confidence that 99% of the population meets the specification	Pass	Pass
Non- CT Extension Leg to Trifurcate	Tensile strength must be greater than 5 lbs with 95% confidence that 99% of the population meets the specification	Pass	Pass	Tensile strength must be greater than 5 lbs with 95% confidence that 99% of the population meets the specification	Pass	Pass

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Summary of Verification Activities (continued)

Test	Proposed Device Acceptance Criteria	Proposed 6F Triple Catheter (K093406) T=0	Proposed 6F Triple Catheter (K093406) T=1	Predicate Device Acceptance Criteria	AngioDynamics Morpheus® CT PICC and Procedure Kits (K070615, K060887, K041420, K040446, K031626, K030415) T=0	AngioDynamics Morpheus® CT PICC and Procedure Kits (K070615, K060887, K041420, K040446, K031626, K030415) T=1
CT Extension Leg to Trifurcate	Tensile strength must be greater than 5 lbs with 95% confidence that 99% of the population meets the specification	Pass	Pass	Tensile strength must be greater than 5 lbs with 95% confidence that 99% of the population meets the specification	Pass	Pass
Shaft to Trifurcate	Tensile strength must be greater than 5 lbs with 95% confidence that 99% of the population meets the specification	Pass	Pass	Tensile strength must be greater than 5 lbs with 95% confidence that 99% of the population meets the specification	Pass	Pass
Catheter Shaft (at nominal OD)	Tensile strength must be greater than 5 lbs with 95% confidence that 99% of the population meets the specification	Pass	Pass	Tensile strength must be greater than 5 lbs with 95% confidence that 99% of the population meets the specification	Pass	Pass

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Summary of Verification Activities (continued)

Test	Proposed Device Acceptance Criteria	Proposed 6F Triple Catheter (K093406) T=0	Proposed 6F Triple Catheter (K093406) T=1	Predicate Device Acceptance Criteria	AngioDynamics Morpheus® CT PICC and Procedure Kits (K070615, K060887, K041420, K040446, K031626, K030415) T=0	AngioDynamics Morpheus® CT PICC and Procedure Kits (K070615, K060887, K041420, K040446, K031626, K030415) T=1
CVP Pressure Monitoring						
Pressure Monitoring	No difference observed between SVS and catheter in mean pressure, systolic pressure and diastolic pressure as compared to predicate devices	Pass	Pass	No difference observed between SVS and catheter in mean pressure, systolic pressure and diastolic pressure as compared to predicate devices	Pass	Pass
Natural Frequency	The natural frequency must be equal to or greater than the predicate device	Pass	Pass	The natural frequency must be equal to or greater than the predicate device	Pass	Pass

Summary of Substantial Equivalence

The 6F Triple Lumen Morpheus® SMART PICC CT and Procedure Kit have been tested and compared to the predicate device. All data gathered demonstrate this device is substantially equivalent. No new issues of safety or efficacy have been raised.

Additional Information

Material Change

In addition to the previously submitted information, AngioDynamics would like to identify an additional change for the device submitted for the pending 510(k) K093406. A silicone material is used as a processing aid which may leave trace amounts on the device. As a result, this MDX silicone should be identified as a material present and included in the 510(k). All testing previously conducted were on units built with this processing aid and as a result representative of the finished device for which we seek marketing clearance. This was an omission in the original submission.

Biocompatibility Data

MDX Silicone, manufactured by Dow is a commonly used medical grade material. Extensive biocompatibility testing has previously been conducted. The following page provides written authorization to allow the Food & Drug Administration to access these data for purpose of this submission review.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MAR 2 5 2010

AngioDynamics, Incorporated
Ms. Jodi Lynn Frasier
Senior Regulatory Affairs Professional
Access Business Unit
603 Queensbury Avenue
Queensbury, New York 12804

Re: K093406
Trade/Device Name: Morpheus® SMART PICC CT and Procedure Kit
Regulation Number: 21 CFR 880.5970
Regulation Name: Percutaneous, Implanted, Long-Term Intravascular Catheter
Regulatory Class: II
Product Code: LJS
Dated: March 1, 2010
Received: March 2, 2010

Dear Ms. Frasier:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 6

Statement of Indications For Use

INDICATIONS FOR USE

510(k) Application: Special 510K Application

Device Name: AngioDynamics, Inc. Morpheus® SMART PICC CT and Procedure Kit

Indications for Use:

The AngioDynamics, Inc. Morpheus® SMART PICC CT and Procedure Kit is indicated for short or long term peripheral access to the central venous system for intravenous therapy, power injections of contrast media, and allows for central venous pressure monitoring. For blood sampling, infusion, or therapy use a 4 French or larger catheter. For central venous pressure monitoring, it is recommended that catheter lumen of 20 gauge or larger be used.

Prescription Use ___X_____ **OR** **Over-the-Counter Use** _____
(Per 21 CFR 801.109)

Please do not write below this line - continue on another page if needed

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K093406